

Applicants find no teaching, suggestion or reference by Johansson et al of a method for treating insulin resistance in a patient with Metabolic Syndrome by decreasing insulin resistance. Johansson et al teach that growth hormone deficient patients are insulin resistant, while the present invention teaches the use of growth hormones to decrease insulin resistance associated with Metabolic Syndrome. In addition, the 1993 Fowelin et al study relied upon by Johansson et al teach the effects of the use of growth hormone on patients who are insulin sensitive and growth hormone deficient, while the present invention teaches the use of growth hormone to treat individuals who are insulin resistant due to the Metabolic Syndrome. Specifically, Fowelin et al teach that after 26 weeks of growth hormone treatment insulin sensitivity returns to base line value, while the present invention teaches that after 9 months of treatment with growth hormone in Metabolic Syndrome individuals there is a decrease in insulin resistance.

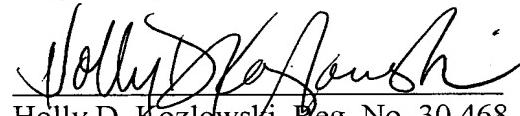
Anticipation under 35 U.S.C. §102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). In view of the failure of Johansson et al to disclose a method for treating insulin resistance in a patient with the Metabolic Syndrome by decreasing insulin resistance, Johansson et al do not disclose each element of the present claims and therefore do not anticipate these claims under 35 U.S.C. §102.

Moreover, references relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). In view of the failure of Johansson et al to teach, suggest or recognize a method for treating insulin resistance in a patient with the Metabolic Syndrome by decreasing insulin resistance, the reference does not provide an enabling disclosure of the present invention, and therefore does not support a rejection of the claims under 35 U.S.C. §103.

It is therefore submitted that the compositions defined by claims 22-24 are neither anticipated by nor rendered obvious over Johansson et al and are patentably distinguishable therefrom, whereby the rejections under 35 U.S.C. §§102 and 103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's rejections under 35 U.S.C. §§ 102 and 103, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



Holly D. Kozlowski, Reg. No. 30,468
Attorney for Applicants
DINSMORE & SHOHL LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568

Version With Markings Showing Changes Made

Please amend the paragraph at page 1, lines 4-10 to read as follows:

The present invention relates to the use of growth hormone, preferably human growth hormone or analogues thereof for the manufacturing of a medicament for treatment of individuals with [the] Metabolic [syndrome] Syndrome (also labeled Syndrome X). They include individuals with abdominal/visceral obesity and its metabolic and circulatory consequences including insulin resistance, lipoprotein aberrations and hypertension. The medicament is also used to increase insulin sensitivity and for treatment and prevention of non-insulin dependent diabetes mellitus.

Please amend claims 22 and 41 to read as follows:

22. (Fourth Amendment) A method for treating a patient for insulin resistance to decrease the insulin resistance, said patient having [the] Metabolic Syndrome [, wherein said syndrome comprises] comprising Primary Insulin Resistance and abdominal/visceral obesity, wherein said method comprises administering to said patient [in] growth hormone or a functional derivative thereof in [the] an amount effective for decreasing insulin resistance of said patient.

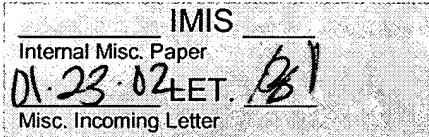
41. (Amended) A method according to claim 22 [of increasing insulin sensitivity of a patient having the Metabolic Syndrome], wherein said method [comprising] comprises administering recombinant human growth hormone at about 9.5 µg/kg daily.

BACKFILE DOCUMENT INDEX SHEET



A DOCPHOENIX

APPL PARTS



IMIS	NPL
Internal Misc. Paper	Non-Patent Literature
01-23-02 ET.	OATH
B1	Oath or Declaration
Misc. Incoming Letter	PET.
	Petition
371P	RETRN
PCT Papers in a 371 Application	Mail Returned by USPS
A...	SEQLIST
Amendment Including Elections	Sequence Listing
ABST	SPEC
Abstract	Specification
ADS	SPEC NO
Application Data Sheet	Specification Not in English
AF/D	TRNA
Affidavit or Exhibit Received	Transmittal New Application
APPENDIX	
Appendix	
ARTIFACT	OUTGOING
Artifact	
BIB	CTMS
Bib Data Sheet	Misc. Office Action
CLM	1449
Claim	Signed 1449
COMPUTER	892
Computer Program Listing	892
CRFL	ABN
All CRF Papers for Backfile	Abandonment
DIST	APDEC
Terminal Disclaimer Filed	Board of Appeals Decision
DRW	APEA
Drawings	Examiner Answer
FOR	CTAV
Foreign Reference	Count Advisory Action
FRPR	CTEQ
Foreign Priority Papers	Count Ex parte Quayle
IDS	CTFR
IDS Including 1449	Count Final Rejection

Internal

SRNT	ECBOX
Examiner Search Notes	Evidence Copy Box Identification
CLMPTO	WCLM
PTO Prepared Complete Claim Set	Claim Worksheet
	WFEE
	Fee Worksheet

NPL

Non-Patent Literature

OATH

Oath or Declaration

PET.

Petition

RETRN

Mail Returned by USPS

SEQLIST

Sequence Listing

SPEC

Specification

SPEC NO

Specification Not in English

TRNA

Transmittal New Application

CTNF

Count Non-Final

CTRS

Count Restriction

EXIN

Examiner Interview

M903

DO/EO Acceptance

M905

DO/EO Missing Requirement

NFDR

Formal Drawing Required

NOA

Notice of Allowance

PETDEC

Petition Decision

INCOMING

AP.B

Appeal Brief

C.AD

Change of Address

N/AP

Notice of Appeal

PA..

Change in Power of Attorney

REM

Applicant Remarks in Amendment

XT/

Extension of Time filed separate

File Wrapper

FWCLM

File Wrapper Claim

IIFW

File Wrapper Issue Information

SRFW

File Wrapper Search Info



PYD/ZB/50 (9/2/2000)

Approved for use through xx/xx/xxxx. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

**REQUEST
FOR
CONTINUED EXAMINATION (RCE)
TRANSMITTAL**

Subsection (b) of 35 U.S.C. §132, effective on May 29, 2000, provides for continued examination of a utility or plant application filed on or after June 8, 1995.

See The American Inventors Protection Act of 1999 (AIPA).

<i>Application Number</i>	09/60,366
<i>Filing Date</i>	March 31, 1998
<i>First Named Inventor</i>	Gudmundur Johansson et al
<i>Group Art Unit</i>	1653
<i>Examiner Name</i>	F. Moezie
<i>Attorney Docket Number</i>	10806-181

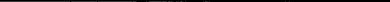
This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

- RECEIVED
TECH CENTER 1600/2000
JAN 25 2002

 1. Submission required under 37 C.F.R. §1.114
 - a. Previously submitted
 - i. Consider the amendment(s)/reply under 37 C.F.R. §1.116 previously filed on _____
(Any unentered amendment(s) referred to above will be entered.)
 - ii. Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
 - iii. Other _____
 - b. Enclosed
 - i. Amendment/Reply
 - ii. Affidavit(s)/Declaration(s)
 - iii. Information Disclosure Statement (IDS)
 - iv. Two Month Extension
 - v. Appointment of Associate Attorneys and Change of Correspondence Address
 2. Miscellaneous
 - a. Suspension of action on the above-identified application is requested under 37 C.F.R. §1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. §1.17(i) required.)
 - b. Other _____
 3. Fees The RCE fee under 37 C.F.R. §1.17(e) is required by 37 C.F.R. §1.114 when the RCE is filed.
 - a. The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. _____
 - i. RCE fee required under 37 C.F.R. §1.17(e)
 - ii. Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)
 - iii. Other _____
 - b. Check in the amount of \$ 1140.00 enclosed
 - c. The Director is hereby authorized to charge any deficiencies, or credit any overpayments, to Deposit Account No. 04-1133

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT REQUIRED

Name (Type/Print)	Holly D. Kozlowski	Registration No. (Attorney/Agent)	30,468
Signature		Date	November 19, 2001

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on the below date.

Name (Type/Print)	Holly D. Kozlowski
Signature	
	Date
	November 19, 2001

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND COMPLETED FORMS TO THE FOLLOWING ADDRESS: Commissioner for Patents, Box RCE, Washington, DC 20231.